Amendments to the Drawings:

The attached replacement sheet includes changes to Fig. 1. Fig. 1 is amended to identify an exemplary flexible section 80 and knee opening 81.

REMARKS

Claims 1, 14, 15, 17, 18, 22, 24-26, 28 and 29 are amended. Claim 31 is added. Claims 2, 21, 23 and 27 are cancelled without prejudice. Upon entry of this amendment, claims 1, 3-20, 22-26 and 28-31 will be pending.

Claim Amendments in General

Independent claims 1, 15, 18, 22, 25 and 29 are amended to emphasize that the apparatus of this invention is for carrying out sequential compression vascular therapy on a limb of a patient. These claims further state that applicant's sleeve includes a first portion (e.g., a thigh portion) with a first expandable chamber and a second portion (e.g., calf portion) with second and third expandable chambers. The three expandable chambers are arranged with respect to each other lengthwise along the sleeve to move blood lengthwise of the limb. Further, the claims are amended to state that the sleeve is torn along perforations to completely remove the first portion of the sleeve from the second portion of the sleeve while leaving the second portion of the sleeve intact for delivery of fluid from the pressurized source to the second and third expandable chambers, also arranged with respect to each other lengthwise along the sleeve, to permit sequential compression vascular therapy on the limb after the first portion of the sleeve is removed.

What applicant has achieved is surprising. Normally, tearing an article apart destroys the unity of the device and its functionality. However, applicant has used what would ordinarily be considered to be a destructive action and turned it into an advantage. Specifically, applicant has invented a compression sleeve which is intentionally designed to be torn apart, thereby irreversibly destroying the unity of the sleeve, while still leaving one portion intact and capable of carrying out sequential compression on the limb of a patient. The surprising and unpredictable nature of this result is strong evidence of non-obviousness. *KSR International Co. v. Teleflex Inc.*

The benefits of the present invention include greater comfort for the patient and reduced cost to the hospital. For example, a patient may be prescribed a mixed vascular therapy starting with the use of a full-length compression sleeve, followed by a period of time using a knee-length sleeve. With the tear-away perforations of the present

invention, there is no need for the hospital to replace the full-length sleeve with a new knee-length sleeve. The patient can use the same sleeve (with the thigh portion removed) to complete the prescribed sequential compression vascular therapy. Removal of a portion of the sleeve also increases the comfort and mobility of the patient. These many advantages and commercial success of applicant's product further support the non-obviousness of applicant's claimed invention.

Claims 14, 17, 24, 26, 28, 29 and 31 are also amended to recite additional details of applicant's compression apparatus, as discussed later.

Claim Rejections - 35 USC §103

Claims 1, 3-7, 11-15, 18-20, 22, 24-26 and 28 are rejected as unpatentable over Islava (6,719,711) and Poole et al. (4,624,248).

The Islava patent is directed to an inflatable splint which is used to immobilize a broken limb such as an arm. The Islava device has two or more rows of latitudinal air chambers 22 which are inflated by conventional blow spout 18. The rows of chambers are separated by perforated welds 40, 42 along which the splint may be torn partially across the splint to form two U-structures which can be used as shown in Figs. 3 and 4. The U-structures thus formed remain connected by a central hinge area 29 of the splint. Islava fails to show or suggest applicant's claimed compression device for a number of reasons.

First, Islava's splint is not constructed to carry our sequential compression vascular therapy on a patient. It will be noted in this regard, that the three expandable chambers in applicant's sleeve are arranged with respect to each other lengthwise along the sleeve so that sequential expansion of the chambers moves blood lengthwise of the limb of a patient. Further, applicant's sleeve is configured such that the second portion of the sleeve (incorporating two of the expandable chambers arranged with respect to each other lengthwise along the sleeve) remains intact after the first portion of the sleeve is torn away. As a result, the second portion of the sleeve may be used to continue a sequential compression vascular therapy by sequentially expanding the second and third

chambers. Islava's chambers are not arranged to permit any such operation, either before or after the splint is torn.

Further, unlike applicant's claimed design where the perforations extend continuously across the sleeve to allow a first portion of the sleeve to be completely removed, the entire emphasis in Islava is toward only a partial tearing of the splint along the perforated weld 40, 42. In this way, a center portion 29 of the splint remains intact so that it can function as a hinge. See for example column 4, lines 1-5, stating that in the preferred embodiment, the latitudinal welds do not extend across the entire width of the splint so that a center portion of the splint remains undivided; column 4, lines 53-61, stating that the center portion shown in Fig. 1a serves as a flexure upon which the two U-shaped portions 50, 60 bend toward or away from one another; and column 6, lines 27-29, stating that the center portions shown in Fig. 6 serve to couple the rows of air chambers together and thus keep the splint as "one integral piece."

The examiner contends that Islava suggests completely removing one portion of the splint from another based on the following statement in col. 4, lines 53-55:

> "detaching one portion 50 from another portion 60 also enables each portion to form a structure independently from the other."

The examiner suggests that "if the different portions were not completely removable they would not be 'independent' as recited." Applicant respectfully disagrees.

First of all, the quoted passage is taken from a paragraph which leads off referring to the construction "shown in Figs. 1a, 1b and 3." Figs. 1a and 1b show that the perforated welds 40, 42 do not extend through the central portion 29 of the sleeve. The patent further states later in that same paragraph (lines 59-61):

> "By detaching the portions 50, 60 along the perforated weld 40, the second portion 60 may be folded into a U-structure first while the first portion remains unfolded, or vice versa. The unwelded center portion 29, as shown in Fig. 1a, serves as the flexure upon which the two portions 50, 60 bend toward or away from one another."

It is apparent from this passage that the two portions 50, 60 remain connected by the hinge portion 29 even after the portions 50, 60 are "detached" and folded into U-structures.

Thus, the word "independently" used in the passage quoted by the examiner does not mean that the two splint portions 50, 60 can be completely separated from one another, but instead means that the two splint portions can be formed into separate U-structures which can moved relative to one another and used to cover two different portions of a limb. This conclusion is further supported by the following statement in col. 5, lines 10-14 of Islava:

> "The perforated latitudinal weld 40 allows one portion 50 to be partially detached from another portion 60 so as to enable the portions 50, 60 to bend toward or away from each other while independently maintaining their respective U-structures." (Emphasis supplied)

Nor would it have been obvious to one of ordinary skill to completely and irreversibly separate the two portions 50, 60 of Islava. The express purpose of Islava's splint is to immobilize and stabilize an injured limb, particularly a bent limb as shown in Figs. 3 and 4 (see col. 1, lines 54-61; col. 5, lines 1-5). To do this, the splint is designed to "encompass" and "envelop" the joint after the splint is partially torn (see col. 4, lines 27-31 and col. 5, lines 18-21). Clearly, the hinge portion 29 assists in achieving these objectives, i.e., immobilizing, stabilizing, encompassing and enveloping the joint after the splint is partially torn to form two U-structures. On the other hand, tearing through the hinge portion 29 and thus destroying it would eliminate the ability of the splint to immobilize, stabilize, encompass and envelop the injured limb at the joint.

Still further, the skilled person would recognize that if Islava's perforated weld 40 were extended to run continuously across the splint from one side of the splint to an opposite side of the splint, i.e., through the hinge 29, the splint could not be properly inflated because the weld 40 would block the flow of air into the air chambers located on the side of the weld opposite the blow spout 18. Alternatively, if an air passage was

provided across the weld to allow inflation of all air chambers, then tearing along the perforations would breach the passage and the entire splint would deflate. In short, any attempt to extend the perforated weld 40 completely across the splint would render the splint inoperable for its intended purpose. (See MPEP 2143.01(V) stating that "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.) For this additional reason, Islava cannot possibly teach a complete separation of the portions 50, 60 from one another.

The examiner also relies on Poole et al. in making his rejection. Poole et al. describe a pressure garment which is used to counteract internal bleeding conditions and hypovolemia "by developing an encircling pressure around the legs and abdomen of a victim" (col. 1, lines 13-15). The garment is divided into an upper section 12 adapted to be operatively positioned around the wearer's abdomen, and a pair of lower sections 14 adapted to be similarly positioned around the wearer's legs (col. 2, lines 25-29). The two sections 12, 14 are detachably interconnected by mating zipper components 16. The zipper connections are designed to be opened to allow medical personnel to gain access to certain arteries located for example at 38 (column 3, lines 14-18). Further, the zipper connections 16 allow for easy replacement of damaged modular components without having to scrap the entire garment (column 3, lines 22-25).

The examiner contends that it would have been obvious in view of Poole et al. to extend the perforations of Islava's sleeve continuously across the sleeve to completely separate the different portions of the sleeve. Applicant respectfully disagrees. As noted above, completely separating the two portions 50, 60 of Islava's splint would destroy the hinge 29. Further, tearing across the unwelded hinge 29 of Islava's design would result in deflation of the splint, rendering the device useless for its intended purpose. Under these circumstances, the skilled person would never modify Islava in the manner suggested by the examiner.

Further, like Islava, Poole et al. completely fails to teach applicant's claimed construction in which first, second and third expandable chambers are arranged with respect to each other lengthwise along the sleeve such that sequential expansion of the chambers moves blood lengthwise of the limb. Instead, the garment described in Poole et

al. comprises an abdomen section 12 having a chamber 22 and two leg sections 14 with chamber 22'. The abdomen chamber 22 is arranged longitudinally with respect to the two leg chambers 22', but the two leg chambers 22' are arranged laterally with respect to one another, not lengthwise relative to one another. This difference is important. The advantage of applicant's claimed longitudinal chamber arrangement is that the second portion of the sleeve can be used to carry out a sequential compression vascular therapy even after the first portion of the sleeve is removed from the second portion of the sleeve. This is accomplished by sequentially inflating the two (or more) chambers of the second portion of the sleeve, these chambers are also arranged with respect to each other lengthwise along the sleeve to move blood lengthwise of the limb. In contrast, if the abdomen section 12 of Poole et al.'s garment is removed, the only remaining expandable chambers are the two leg chambers 22', and these are arranged side-by-side on two different sleeves, not lengthwise with respect to one another to move blood along the length of the limb.

For at least these reasons, claims 1, 3-7, 11-15, 18-20, 22, 24-26 and 28 are not obvious in view of Islava and Poole et al., whether considered individually or in combination.

Claims 8-10 are rejected as unpatentable over the references as applied to claim 1 and further in view of Dye (5,795,312).

Dye shows a compression sleeve with a plurality of longitudinally disposed inflatable chambers 38a-38f. Dye fails to disclose perforations extending across the sleeve to allow the sleeve to be completely torn to remove one portion from the other. Accordingly, claims 8-10, which depend either directly or indirectly from claim 1, are submitted to be patentable for at least the same reasons as claim 1.

Claims 1, 3-11, 13-20, 22, 24-26 and 28-30 are rejected as unpatentable over Dye (5,795,312) in view of Islava (6,719,711), Poole et al. (4,624,248) and Arkans (6,062,244).

The examiner contends that it would have been obvious to separate different parts of Dye's sleeve from one another in order to accommodate different needs of different

patients. Applicant respectfully disagrees. Full length and knee length compression sleeves for use in vascular therapy have been sold separately for many years. The concept of using one sleeve which can be torn apart and still function as claimed by applicant is unique. Indeed, surprising.

Nor would it have been obvious in view of either Islava or Poole et al. to modify Dye to include applicant's claimed perforations. As explained above, Islava's perforations do not extend completely and continuously across the splint. Rather, the perforations are configured for allowing two U-structures to be independently formed and moved while remaining connected by the hinge 29. Thus, Islava actually teaches away from modifying Dye as the examiner contends.

The Poole et al. patent is directed to a garment having modular sections 12, 14 that can be connected, disconnected *and reconnected*. The patent emphasizes the advantage of this arrangement, as follows:

> "... the zipper connections 16 are designed to be opened to allow medical personnel to gain access to critical arteries..." (col. 3, lines 14-16)
>
> "The zipper connections 16 allow for easy replacement of damaged modular components, without having to scrap the entire garment." (col. 3, lines 22-25.)

Thus, at first glance, Poole et al. might suggest the possibility of modifying Dye to include a zipper to permit disconnection and reconnection of two parts of the compression sleeve. But a zipper connection is a far cry from using perforations to tear one sleeve portion from another. Disconnection by tearing, which destroys the connection of the sleeve portions and negates reattachment, would defeat the very reason for using a zipper connection in the first place. It would be entirely inappropriate and counter to the purpose of the Poole et al. invention to include "tear away" connections between the components.

Applicant's also disagrees with the examiner's contention that the Poole et al. reference teaches "being able to remove one section of the sleeve to be able to use the remaining sleeve alone as desired." In use, the abdomen and leg sections 12, 14 of Poole